UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

WARNING LETTER

Date: May 19, 2021

TO: adl@biocence.com biocence.com@domainprivacygroup.com – BGP, LLC
2118 Wilshire Blvd
#766
Santa Monica, CA 90403

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address www.biocence.com on February 9, 2021 and May 11, 2021. We have also reviewed your social media websites at

to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 and other conditions in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 and other conditions.

Examples of claims observed on the "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" product label and labeling that provide evidence of the intended uses (as defined in 21 CFR 201.128) of your product, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 and other conditions include but may not be limited to, the following:

- "Effective against COVID-19!" [from the "Bio" section of your Instagram account at www.instagram.com/biocence]
- "ALL BOTANICAL FDA approved OTC product…#fightcovid19" [from a March 31, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence . . . causes a 99.97% reduction of the COVID-19 Virus" [from a July 14, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biopo4 d (-)-6.6 (511)9 (/)-ocial Medi SS1.3 3.5 (ebpag)-11.2 (e)]T on onwww383.4 (.)-6.6 (i)2.6 (ns)

- "Biocence ERADICATES: Pathogen Causing Bacteria 99.99% Pathogen Causing Virus 99.97% Pathogen Causing Fungi 99.99% Pathogen Causing Mold 99.99%" [from a November 9, 2020 post on your Social Media webpage www.facebook.com/Biocence]
- "All the components of the Biocence Botanical Complex have been given a GRAS/E status (Generally Recognized as Safe and Effective) and to date, All Microbes, ie(sic): Gm. Pos/Neg Bacteria (aerobic/anaerobic; cocci/bacilli, vegetative forms and sporiforms); strains of MRSA, VRE, MDRAB; Viruses (including H1N1, Ebola, HIV, HSV, HPV, Pox, enveloped and non- enveloped (sic), RNA/DNA, single and double stranded); Fungi(dermatophytoses, yeasts and molds) have been killed in 30 seconds or less, with the large majority, 'Exploding on Contact.'" (from the brochure that accompanies your product).
- "Biocence can be used as a topical preventative and prophylactic antiseptic; a treatment application for superficial soft-tissue wounds and an inanimate surface wipe-down product; whereas EPA-controlled disinfectants cannot be used, legally, on animate or skin surfaces, human or animal." (from the brochure that accompanies your product).
- "Safely Eradicates 99.9% of Multi-Resistant Organism (MDRO's) that cause majority of HAI's and CAI's in 30 seconds or less.'*' '*In Clinical Studies*'" (from product label)
- "ADVANCE WOUND CARE TECHNOLOGY FOR WOUNDS AND OSTOMY SITES . . . Designed To Give Protection through Prevention with Treatment . . . Apply and Let Dry" (from product label)

Based on the above claims, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is a drug as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. § 321(g)(1)(C), because it is intended to affect the structure or any function of the body. Specifically, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is intended for use as both a consumer and a health care personnel topical antiseptic.

This topical antiseptic product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. § 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for this product, as further described below) or under other exceptions not applicable here

product . . .#fightcovid19." As noted above, your product does not have any FDA approved application on file. Further to state that any drug product is "FDA APPROVED REGISTRY" is inaccurate; drugs are subject to listing with FDA, not registration. Moreover, registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or any other drugs of the establishment, nor does it mean that a product may be legally marketed, 21 CFR 207.77(a). This language is misleading given that the general public is not likely to be familiar with the details of FDA regulation. Thus, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is misbranded under section 502(a) of the FD&C Act, 21 U.S.C. § 352(a), because its labeling is false or misleading in any particular.

Lastly, this product is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. § 352(ee), because "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is subject to section 505G of the FD&C Act, 21 U.S.C. § 355h, but does not comply with the requirements for marketing under that section and is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. § 355.

The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. § 331(a).

You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19 or other disease related use for which they have not been approved by FDA, and that you do not make claims that misbrand your products in violation of the FD&C Act. **Within 48 hours, please send an email to** **COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your f

Lastly, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $43,792 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please6 (he)8.9 [(a2 (t e13.5 (ho ,)-6.6 D2.6 (s)-2 (i)2.6 (S

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,